

Atty. Dkt. No. 033948-0126

ifu

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: GARDNER, David K. and LANE,
Michelle T.

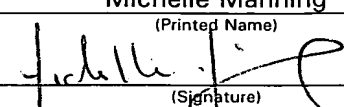
Title: MAMMALIAN GAMETE AND
EMBRYO CULTURE MEDIA
SUPPLEMENT AND METHOD
OF USING SAME

Appl. No.: 10/764,821

Filing Date: 01/26/2004

Examiner: J. Eric Angell

Art Unit: 1635

CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below. Michelle Manning (Printed Name)  (Signature) June 28, 2004 (Date of Deposit)
--

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop MISSING PARTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith on Form PTO-1449 a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 C.F.R. § 1.56, including the documents cited by or submitted to the United States Patent & Trademark Office in parent application Serial No. 09/877,395. As provided in 37 C.F.R. §1.98(d), copies of the documents cited or submitted during the prosecution of application Serial No. 09/877,395, filed 06/08/2001, are not being provided since they were previously submitted to the United States Patent & Trademark Office. A copy of each remaining non-U.S. patent and non-U.S. patent application document is being submitted to comply with the provisions of 37 C.F.R. §§ 1.97 and 1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statement in a patent application filed after June 30, 2003 and in an

international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003*.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The Form PTO-1449 and accompanying documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

An English translation of the single foreign-language document (EP 0220379) is not readily available. However, an English language abstract of the foreign language document is included with the foreign-language document.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

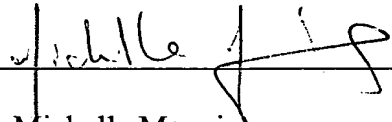
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-2350. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or

even entirely missing, the Commissioner is authorized to charge the unpaid amount to
Deposit Account No. 50-2350.

Respectfully submitted,

Date June 28, 2004

FOLEY & LARDNER LLP
Customer Number: 23524
Telephone: (608) 258-4305
Facsimile: (608) 258-4258

By 

Michelle Manning
Attorney for Applicant
Registration No. 50,592

Form PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

033948-0126

SERIAL NO.

10/764,821

APPLICANT

GARDNER, David K. and LANE, Michelle T.

FILING DATE

01/26/2004

GROUP ART UNIT

1635

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
		4,007,087	02/08/1977	Ericsson			
		4,327,177	04/27/1982	Shrimpton			
		4,804,537	02/14/1989	Bergman et al.			
		5,102,783	04/07/1992	Alkemade et al.			
		5,432,160	07/11/1995	Hara et al.			
		5,496,720	03/05/1996	Susko-Parrish et al.			
		5,612,196	03/18/1997	Becquart et al.			
		5,096,822	03/07/1992	Rosendrants, Jr. et al.			
		6,010,448	01/04/2000	Thompson			
		6,043,092	03/28/2000	Block			
		6,048,728	04/11/2000	Inlow et al.			
		6,130,086	10/10/2000	Nakazawa et al.			
		6,153,582	11/28/2000	Skelnik			
		6,140,121	10/31/2000	Ellington et al.			

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
		WO 86/07377	18 Dec 1986	PCT				
		WO 99/67364	29 Dec 1999	PCT				
		WO 00/32140	8 Jun 2000	PCT				
		WO 92/21234	10 Dec 1992	PCT				
		EP 0 220 379	3 Jul 1986	Europe				
		EP 0 248 637	2 Jun 1987	Europe				
		EP 0 521 674	29 Jun 1992	Europe				
		EP 0 872 80	21 Oct 1998	Europe				
		EP 0 947 581	6 Aug 1997	Europe				
		2,199,663	11 Sep 1998	Canada				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Copy of Denmark Search Report No. SE 2003 04710.
		Kane, M. T. <i>et al.</i> , "Protein-Free Culture Medium Containing Polyvinylalcohol, Vitamins, and Amino Acids Supports Development of Eight-Cell Hamster Embryos to Hatching Blastocysts," <i>The Journal of Experimental Zoology</i> , Vol. 247, pp. 183-187, 1988; Alan R. Liss, Inc.

Form PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 033948-0126	SERIAL NO. 10/764,821
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		APPLICANT GARDNER, David K. and LANE, Michelle T.	
		FILING DATE 01/26/2004	GROUP ART UNIT 1635
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
		McKiernan, S. H. <i>et al.</i> , "Different Lots of Bovine Serum Albumin Inhibit or Stimulate in Vitro Development of Hamster Embryos," <i>In Vitro Cell Dev. Biol.</i> , Vol. 28A, pp. 154-156, March 1992; Tissue Culture Association.	
		Batt, P. A., <i>et al.</i> , "Oxygen Concentration and Protein Source Affect the Development of Preimplantation Goat Embryos <i>In Vitro</i> ," <i>Reprod. Fertil. Dev.</i> , Vol. 3, pp. 601-607, 1991.	
		Kane, M. T., "Minimal Nutrient Requirements for Culture of One-Cell Rabbit Embryos," <i>Biology of Reproduction</i> , Vol. 37, pp. 775-778, 1987.	
		Gray, C. W. <i>et al.</i> , "Purification of an Embryotrophic Factor From Commercial Bovine Serum Albumin and Its Identification as Citrate," <i>J. Reprod. Fert.</i> , Vol. 94, pp. 471-480, 1992; Journals of Reproduction & Fertility, Ltd., Great Britain.	
		Farrar, N.C. <i>et al.</i> , "Effects of Serum or Fatty Acid Supplementation of Synthetic Oviduct Fluid Medium on Development of Bovine Embryos <i>In Vitro</i> ," Abstract from a presentation at a meeting of the British Society of Animal Science, September 1999.	
		Hooper, K. <i>et al.</i> , "Toward Defined Physiological Embryo Culture Media: Replacement of BSA with Recombinant Albumin," <i>Biology of Reproduction</i> , Vol. 62, (Suppl. 1), p. 249 (Abstract), from 33 rd Annual Meeting of Society for the Study of Reproduction, July 15-18, 2000, University of Wisconsin.	
		Gardner, D. <i>et al.</i> , "Recombinant Human Serum Albumin and Hyaluronan Can Replace Blood-Derived Albumin in Embryo Culture Media," <i>American Society for Reproductive Medicine</i> , Vol. 74, No. 3S, p. S31 (Abstract), from 56 th Annual Meeting of the American Society for Reproductive Medicine, October 21-26, 2000, San Diego, California.	
		Gardner, D. <i>et al.</i> , "Bovine Oocyte Maturation in a Completely Defined Medium: Replacing Serum with Recombinant Albumin and Hyaluronan," <i>Theriogenology, An international Journal of Animal Reproduction</i> , Vol. 55, No. 1, p. 471 (Abstract), from Proceedings of the Annual Conference of the International Embryo Transfer Society, January 13-16, 2001, Omaha, Nebraska.	
		Gardner, D. K. <i>et al.</i> , "Culture of viable human blastocysts in defined sequential serum-free media," <i>Human Repro.</i> , Vol. 13, Suppl. 3, June 1998, pp. 148-159; European Society for Human Reproduction and Embryology.	
		Keenan, J. <i>et al.</i> , "Recombinant human albumin in cell culture: Evaluation of growth-promoting potential for NRK and SCC-9 cells in vitro," <i>Cytotechnology</i> , Vol. 24, No. 3, 1997, pp. 243-252; published by Kluwer Academic Publishers.	
		Kjems, E. <i>et al.</i> , "Isolation of hyaluronic acid from cultures of streptococci in a chemically defined medium," <i>Acta Pat. Microbiol. Scand., Sect. B</i> , Vol. 84:162-164, 1976.	
		Gene Characterization Kits, <i>Stratagene Catalog</i> , 1988, p. 39.	
		Miyano, T. <i>et al.</i> , "Effects of Hyaluronic Acid on the Development of 1- and 2-Cell Porcine Embryos to the Blastocyst Stage in Vitro," <i>Theriogenology</i> , Vol. 41, pp. 1299-1305, 1994; Butterworth-Heinemann.	
		Quinn, P. <i>et al.</i> , "Improved Pregnancy Rate in Human In Vitro Fertilization with the Use of a Medium Based on the Composition of Human Tubal Fluid," <i>Fertility and Sterility</i> , Vol. 44, No. 4, pp. 493-498, 1985; The American Fertility Society..	
		Roth, E. <i>et al.</i> , "Influence of Two Glutamine-Containing Dipeptides on Growth of Mammalian Cells," <i>In Vitro Cellular & Devel. Biol.</i> , Vol. 24, No. 7, pp. 696-698, 1988; Tissue Culture Association, Inc.	
		Jones, G. M. <i>et al.</i> , "Evolution of a Culture Protocol for Successful Blastocyst Development and Pregnancy," <i>Human Repro.</i> , Vol. 13, No. 1, pp. 169-177, 1998; European Society for Human Reproduction and Embryology.	
		Gardner, D. K. <i>et al.</i> , "Concentrations of Nutrients in Mouse Oviduct Fluid and Their Effects on Embryo Development and Metabolism In Vitro," <i>J Repro & Fert.</i> , Vol. 88, pp. 361-368, 1990; Journals of Reproduction & Fertility Ltd., printed in Great Britain.	

		Hammit, D. G. <i>et al.</i> , "Improved Methods for Preparation of Culture Media for <i>in-vitro</i> Fertilization and Gamete Intra-Fallopian Transfer," <i>Human Repro.</i> , Vol. 5, No. 4, pp. 457-463, 1990; Oxford University Press.
		Leese, H. J., "The Environment of the Preimplantation Embryo," from <i>Establishing a Successful Human Pregnancy</i> , Serono Symposia Publications from Raven Press, Vol. 66, pp. 143-154, 1990; R. G. Edwards (ed.), Raven Press, New York.
		Yovich, J. <i>et al.</i> , <i>The Management of Infertility: A Manual of Gamete Handling Procedures</i> , pp. 106-195, 1990; John Yovich and Geddis Grudzinskas, Oxford.
		Lane, M. <i>et al.</i> , "Effect of Incubation Volume and Embryo Density on the Development and Viability of Mouse Embryos In Vitro," <i>Human Repro.</i> , Vol. 7, No. 4, pp. 558-562, 1992; Oxford University Press.
		Gardner, D. K. <i>et al.</i> , "Mouse Embryo Cleavage, Metabolism and Viability: Role of Medium Composition," <i>Human Repro.</i> , Vol. 8, No. 2, pp. 288-295, 1993; Oxford University Press.
		Gardner, D. K. <i>et al.</i> , "Embryo Culture Systems," <i>Handbook of In Vitro Fertilization</i> , Trounson & Gardner (eds.), pp. 85-114, 1993; CRC Press.
		Gardner, D. K. <i>et al.</i> , "Amino Acids and Ammonium Regulate Mouse Embryo Development in Culture," <i>Biol. Repro.</i> , Vol. 48, pp. 377-385, 1993.
		Lane, M. <i>et al.</i> , "Increase in Postimplantation Development of Cultured Mouse Embryos by Amino Acids and Induction of Fetal Retardation and Exencephaly by Ammonium Ions," <i>J. Repro. & Fertility</i> , Vol. 102, pp. 305-312, 1994; Journals of Reproduction & Fertility Ltd.
		Gardner, D. K. <i>et al.</i> , "Enhanced Rates of Cleavage and Development for Sheep Zygotes Cultured to the Blastocyst Stage In Vitro in the Absence of Serum and Somatic Cells: Amino Acids, Vitamins, and Culturing Embryos in Groups Stimulate Development," <i>Biol Repro.</i> , Vol. 50, pp. 390-400, 1994.
		Gardner, D. K., "Mammalian Embryo Culture in the Absence of Serum or Somatic Cell Support," <i>Cell Biol.Int'l</i> , Vol. 18, No. 12, pp. 1163-1179, 1994; Academic Press Ltd.
		Barnes <i>et al.</i> , "Blastocyst Development and Birth After In-Vitro Maturation of Human Primary Oocytes, Intracytoplasmic Sperm Injection and Assisted Hatching," <i>Human Repro.</i> , pp. 3243-3247, 1995; published by Oxford Univ. Press, Oxford.
		Gardner, D. K. <i>et al.</i> , "Alleviation of the '2-Cell Block' and Development to the Blastocyst of CF1 Mouse Embryos: Role of Amino Acids, EDTA and Physical Parameters," <i>Human Repro.</i> , Vol. 11, No. 12, pp. 2703-2712, 1996; European Society for Human Reproduction and Embryology.
		O'Brien, J. K. <i>et al.</i> , "Developmental Capacity, Energy Metabolism and Ultrastructure of Mature Oocytes from Prepubertal and Adult Sheep," <i>Repro. Fertil. Dev.</i> , Vol. 8, pp. 1029-1037, 1996.
		Schramm, R. D. <i>et al.</i> , "Development of in-vitro-fertilized Primate Embryos into Blastocysts in a Chemically Defined, Protein-Free Culture Medium," <i>Human Repro.</i> , Vol. 11, No. 8, pp. 1690-1697, 1996; published by European Society for Human Reproduction and Embryology.
		Gardner, D. <i>et al.</i> , "Complex Physiologically Based Serum-Free Culture Media Increase Mammalian Embryo Development", from 10 th World Congress on In Vitro Fertilization and Assisted Reproduction, Vancouver, Cana, May 24-28, 1997, pp. 187-191; Monduzzi Editore S.p.A. - Bologna (Italy).
		Gardner, D. K. <i>et al.</i> , "Culture and Selection of Viable Blastocysts: A Feasible Proposition for Human IVF?," <i>Human Repro Update</i> , Vol. 3, No. 4, pp. 367-382, 1997; European Society for Human Reproduction and Embryology.
		Lane, M. <i>et al.</i> , "Differential Regulation of Mouse Embryo Development and Viability by Amino Acids," <i>J. Repro. & Fertility</i> , Vol. 109, pp. 153-164, 1997; Journals of Reproduction & Fertility Ltd.
		Lane, M. <i>et al.</i> , "Animal Experimentation: Nonessential Amino Acids and Glutamine Decrease the Time of the First Three Cleavage Divisions and Increase Compaction of Mouse Zygotes In Vitro," <i>J. Assisted Repro. and Genetics</i> , Vol. 14, No. 7, pp. 398-403, 1997; Plenum Publishing Corporation.
		Abeyderra, L. R. <i>et al.</i> , "Fertilization and Subsequent Development <i>In Vitro</i> of Pig Oocytes Inseminated in a Modified Tris-Buffered Medium with Frozen-Thawed Ejaculated Spermatozoa," <i>Biol. Repro.</i> , Vol. 57, pp. 729-734, 1997.
		Keskintepe, L. <i>et al.</i> , "Caprine Blastocyst Formation Following Intracytoplasmic Sperm Injection and Defined Culture," <i>Zygote</i> , Vol. 5 (August), pp. 261-265, 1997; Cambridge University Press.

		Gardner, D. K. <i>et al.</i> , "Culture and Transfer of Human Blastocysts Increases Implantation Rates and Reduces the Need for Multiple Embryo Transfers," <i>Fertility and Sterility</i> , Vol. 69, pp. 84-88, 1998; Elsevier Science, New York.
		Gardner, D. K., "Development of Serum-Free Media for the Culture and Transfer of Human Blastocysts," <i>Human Repro.</i> Vol. 13, Suppl. 4, pp. 218-225, 1998; European Society for Human Reproduction and Embryology.
		Gardner, D. K. <i>et al.</i> , "Elimination of High-Order Multiple Gestations by Blastocyst Culture and Transfer," <i>Female Infertility Therapy: Current Practice</i> , Z. Shoham <i>et al.</i> , eds., pp. 267-274, 1998; Martin Dunnitz, London.
		Gardner, D. K., "Improving Embryo Culture and Enhancing Pregnancy Rate," <i>Female Infertility Therapy: Current Practice</i> , Z. Shoham <i>et al.</i> , eds., pp. 283-299, 1998; Martin Dunnitz, London.
		Gardner D. <i>et al.</i> , "Controversies in Assisted Reproduction and Genetics: Human Embryo Viability: What Determines Developmental Potential, and Can It Be Assessed?," <i>J. Assisted Repro. & Genetics</i> , Vol. 15, No. 8, pp. 455-458, 1998; Plenum Publishing Corporation.
		Gardner, D. K., "Changes in Requirements and Utilization of Nutrients During Mammalian Preimplantation Embryo Development and Their Significance in Embryo Culture," <i>Theriogenology</i> , Vol. 49, pp. 83-102, 1998; Elsevier Science, Inc.
		Lane, M. <i>et al.</i> , "Amino Acids and Vitamins Prevent Culture-Induced Metabolic Perturbations and Associated Loss of Viability of Mouse Blastocysts," <i>Human Repro.</i> , Vol. 13, No. 4, pp. 991-997, 1998; European Society for Human Reproduction and Embryology.
		Gardner, D. K., "Embryo Development and Culture Techniques," <i>Animal Breeding. Technology for the 21st Century</i> , A. J. Clark, ed., pp. 13-46, 1998; Harwood Academic Publishers.
		Staessen, C. <i>et al.</i> , "Controlled comparison of commercial media for human in-vitro fertilization: Ménézo B2 medium versus Medi-Cult universal and BM1 medium," <i>Human Repro.</i> , Vol. 13, No. 9, pp. 2548-2554, 1998; European Society for Human Reproduction and Embryology.
		Cited pages from the Gibco catalogue. No other information available.